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FILING DATE.**

APPLICATION NUMBER: 60/499,818

FILING DATE: September 03, 2003

RELATED PCT APPLICATION NUMBER: PCT/US04/24281

Certified by



Jon W Dudas

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17497 U.S. PTO
60/30/03

PTO/SB/16 (05-03)

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53 (c).

Express Mail Label No. EV349859230US

17497 U.S. PTO
60/499818
09/03/03

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| <input type="checkbox"/> Additional inventors are being named on the _____ separately numbered sheets attached hereto | | |
| TITLE OF THE INVENTION (500 characters max) "END CAP FOR A FLUID SAMPLING DEVICE" | | |
| CORRESPONDENCE ADDRESS | | |
| Direct all correspondence to: | | |
| <input checked="" type="checkbox"/> Customer Number OR | 23506 | <input type="checkbox"/> Place Customer Number Bar Code Label here |
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| ENCLOSED APPLICATION PARTS (check all that apply) | | |
| <input checked="" type="checkbox"/> Specification Number of Pages <input checked="" type="checkbox"/> Drawing(s) Number of Sheets <input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76 | 9 2 | <input type="checkbox"/> CD(s), Number <input checked="" type="checkbox"/> Other (specify) <input type="checkbox"/> Return Receipt Postcard |
| METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT | | |
| <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. <input type="checkbox"/> A check or money order is enclosed to cover the filing fees <input checked="" type="checkbox"/> The Director is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: 50-1513 <input checked="" type="checkbox"/> Payment by credit card. Form PTO-2038 is attached. | FILING FEE AMOUNT (\$) 160 | |
| The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government. | | |
| <input checked="" type="checkbox"/> No. <input type="checkbox"/> Yes, the name of the U.S. Government agency and the Government contract number are: _____. | | |

[Page 1 of 2]

Date

9/3/2003

Respectfully submitted,

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39,695

(if appropriate)

Docket Number:

2G02.1-151

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop Provisional Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Patent
Attorney Docket No. 2G02.1-151

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Date: **September 3, 2003**

Signature: Vanessa Lake

PROVISIONAL

APPLICATION FOR LETTERS PATENT

UNITED STATES OF AMERICA

Be it known that **Henry M. Grage, Jr.**, of 425 Brook Manor Court, Alpharetta GA 30022; and **Jack GRIFFIS**, of 1133 Druid Lake, Decatur, both of Georgia, have invented certain new and useful improvements in an

END CAP FOR A FLUID SAMPLING DEVICE

for which the following is a specification.

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END CAP FOR A FLUID SAMPLING DEVICE

Technical Field

[00001] The present invention relates generally to medical devices and procedures, and more particularly to lancing devices for sampling blood or other bodily fluids. The invention more particularly relates to an end cap for use in conjunction with a lancing device that allows for a collection of an increased volume of blood or bodily fluid to be obtained.

Background of the Invention

[00002] Many medical procedures require puncturing of the skin, and sometimes underlying tissues, of an animal or human subject. For example, a sharp lancet tip is commonly used to puncture the subject's skin for sampling of blood or other body fluid, as for example in blood glucose monitoring by diabetics. Generally, lancets are much thinner than traditional hypodermic syringe needles; and therefore result in less pain to the patient.

[00003] However, one common problem that has been found to exist with utilizing thin lancets is the closure of the puncture site before an adequate volume of blood has been collected. Premature closure of the puncture requires additional blood to be drawn from the patient, often in a separate and sometimes less desirable location, resulting in an increase in pain and stress. Costs also increase, as multiple lancets are required to acquire an adequate sample. This is particularly the case when alternate lancing sites other than the fingertips, such as for example the forearm, are lanced.

[00004] Attempts have been made to provide lancing devices that inhibit premature closure of the puncture site. Such past attempts have included the use of an outer ring positioned away from the puncture site to "milk" or apply pressure around the wound to express a larger sample and prevent closure of the skin. Although utilizing the

aforementioned circular ring often allows a larger sample to be collected before closure of the puncture site, occasionally a sample size is still insufficient, and another lancing operation to collect blood or analytic fluid is required.

5 [00005] Thus it can be seen that needs exist for improved lancing devices and methods to provide a mechanism that allows for an increased volume of blood or other analytic fluid to be expressed and collected before the puncture site closes. Needs further exist for such a mechanism that is readily adaptable to current lancing devices and procedures.

Summary of the Invention

10 [00006] In example forms, the present invention is an end cap for a lancing device that allows for an increased volume of blood or other body fluid to be collected from a lancing site on the skin of a human or animal subject. In example embodiments, the device includes a series of raised ribs, which are compressed against the skin's surface around the lancing site to guide blood toward the wound for sample collection. In 15 further embodiments, the invention is a method for increasing bloodflow from a lancing site, the method including compressing a contact surface comprising a series of ribs against the skin around the lancing site, and optionally rotating or twisting the contact surface against the skin around the lancing site

20 [00007] In one aspect, the present invention is a lancing device comprising an end defining an opening for passing a lancet tip, and a contact face with a plurality of spaced ribs adjacent the opening.

25 [00008] In another aspect, the invention is an endcap for a lancing device, the endcap having a first end for mounting to the lancing device, and a second end comprising a contact face with an opening formed therein and at least one rib projecting from the contact face.

- [00009] In still another aspect, the endcap of the present invention includes a plurality of ribs projecting from the contact face in a spaced array.
- [00010] In still another aspect, the ribs are spaced about the opening in a circular array.
- 5 [00011] In another aspect, the invention is a method of sample collection with a lancing device, said method comprising lancing the skin of a subject at a lancing site, and compressing a ribbed contact face of the lancing device against the skin adjacent the lancing site. Optionally, the method further includes twisting the ribbed contact face in connection with the skin.
- 10 [00012] These and other aspects, features and advantages of the invention will be understood with reference to the drawing figures and detailed description herein, and will be realized by means of the various elements and combinations particularly pointed out in the appended claims. It is to be understood that both the foregoing general description and the following brief description of the drawings and detailed description 15 of the invention are exemplary and explanatory of preferred embodiments of the invention, and are not restrictive of the invention, as claimed.

Brief Description of the Drawings

- [00013] FIGURES 1 and 2 show perspective views of an end cap according to one example embodiment of the present invention.
- 20 [00014] FIGURE 3 shows a cross-sectional view of the endcap of Fig. 1.
- [00015] FIGURES 4 and 5 show front and rear views of the end cap of Fig. 1.
- [00016] FIGURE 6 shows another perspective view of an endcap according to the present invention.
- [00017] FIGURE 7 shows a side view of the end cap of Fig. 6.

- [00018] FIGURE 8 shows a cross-sectional view of the end cap of Fig. 6.
- [00019] FIGURES 9 and 10 show front and rear views of the end cap of Fig. 6.
- [00020] FIGURE 11 shows a detailed view of the ribbed contact face of an end cap according to the present invention.
- 5 [00021] FIGURES 12a-12e show detailed views of the ribbed contact face of an end cap according to several alternate embodiments of the present invention.

Detailed Description of Example Embodiments

[00022] The present invention may be understood more readily by reference to the following detailed description of the invention taken in connection with the accompanying drawing figures, which form a part of this disclosure. It is to be understood that this invention is not limited to the specific devices, methods, conditions or parameters described and/or shown herein, and that the terminology used herein is for the purpose of describing particular embodiments by way of example only and is not intended to be limiting of the claimed invention. Also, as used in the specification 10 including the appended claims, the singular forms "a," "an," and "the" include the plural, and reference to a particular numerical value includes at least that particular value, unless the context clearly dictates otherwise. Ranges may be expressed herein as from "about" or "approximately" one particular value and/or to "about" or "approximately" another particular value. When such a range is expressed, another embodiment 15 includes from the one particular value and/or to the other particular value. Similarly, when values are expressed as approximations, by use of the antecedent "about," it will be understood that the particular value forms another embodiment.

20

[00023] With reference now to the drawing figures, an end cap 10 is shown by way of example embodiments of the present invention. The end cap 10 preferably is 25 formed of a substantially rigid body having a longitudinal axis 12 extending from a first

end 14 to a second end 16, wherein the first end 14 is sized and/or shaped to attach to a lancing device. The attachment of the end cap 10 to a lancing device can be accomplished by way of a releasable or permanent coupling such as for example a threaded screw coupling, a socket, snap fittings, adhesive or welding, one or more screws or other connectors, or the like; or the endcap 10 can comprise an integral portion of the overall housing of the lancing device. In an example embodiment, at least a portion of the endcap 10 is formed of a transparent material to allow the patient and/or clinician to view the puncture site during lancing of the skin and collection of the bodily fluid, and thereby monitor the sample size.

10 [00024] The second end 16 of the body 12 defines an opening 18 through which a sharp lancet tip, such as a needle or blade tip, projects to lance the skin of the subject and form a wound at the sample site from which a sample of body fluid is expressed and collected. The opening 18 is preferably sized and shaped to allow passage of the tip of the lancet only, and to prevent the lancet from escaping from the housing of the lancet. The opening 18 is preferably also sized and shaped to prevent bodily fluids such as blood from contacting the end cap 10 during lancing and subsequent collection.

15 [00025] The second end 16 of the body 12 preferably comprises a contact face 20 surrounding or adjacent the opening 18. The contact face is preferably concave, but in alternate embodiments is planar or convex. One or more, and preferably a plurality of discontinuous raised ribs 22 are preferably provided on the contact face 20. The ribs increase the surface contact area between the skin and the contact face and assist in applying tension to the skin at the lancing site to enhance sample collection. The ribs 22 can be arranged in a regularly or irregularly spaced series, and optionally are oriented radially and lie in a generally ring-shaped pattern surrounding the opening 18. In one embodiment of the invention, the ribs 22 are of equal size and shape. In an alternate embodiment, the ribs are of differing lengths, widths and/or depths. In one depicted embodiment, the ribs have a four-sided cross-section when viewed from the

end in the direction of the axis 12, as seen best in Figs. 4 and 11. In alternate embodiments, the ribs are circular, triangular or otherwise configured. For example, Figs. 12b – 12e show various alternate rib embodiments, including radial ribs (Fig. 12b), circular ribs in a pattern similar to dimples on a golf ball (Fig. 12c), annular circumferential ribs (Fig. 12d), and helical spiral ribs (Fig. 12e). The ribs 22 preferably are discontinuous raised features extending across part of the contact face 20, or more preferably across substantially the entire contact face 20 from the outer perimeter edge to the blood expression zone defined by the opening 18, to guide or direct available blood or other fluid in the tissue surrounding the lancing site toward the wound for sample collection.

[00026] The present invention also includes a method of sample collection, the method comprising compressing the ribbed contact face against the skin adjacent the lancing site before and/or after lancing the skin at the lancing site. Optionally, the ribbed contact face can be pumped to stimulate flow of the sampled fluid. Alternatively or additionally, the ribbed contact face is optionally twisted or rotated when in contact with the skin at the sampling site, to increase the skin tension at the sampling site and enhance sample collection. The provision of spaced ribs on the contact surface assists in gripping the skin surface on and between the ribs during this twisting operation.

[00027] While the invention has been described with reference to preferred and example embodiments, it will be understood by those skilled in the art that a variety of modifications, additions and deletions are within the scope of the invention, as defined by the following claims.

CLAIMS

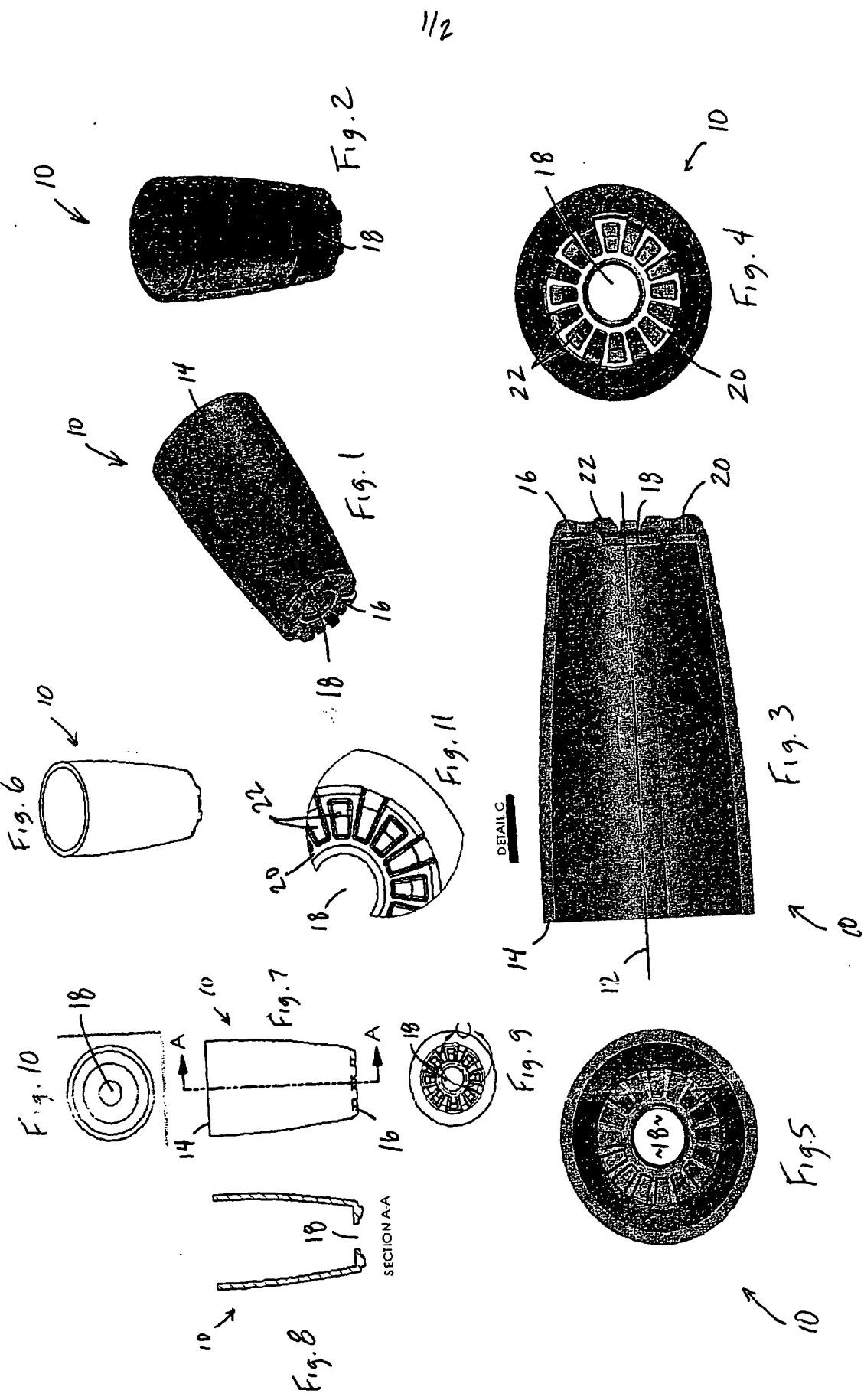
What is claimed is:

1. A lancing device comprising an end defining an opening for passing a lancet tip, and a contact face with a plurality of spaced ribs adjacent the opening.
2. An endcap for a lancing device, the endcap having a first end for mounting to the lancing device, and a second end comprising a contact face with an opening formed therein and at least one rib projecting from the contact face.
3. The endcap of Claim 2, comprising a plurality of ribs projecting from the contact face in a spaced array.
4. The endcap of Claim 3, wherein the ribs are spaced about the opening in a circular array.
5. A method of sample collection with a lancing device, said method comprising lancing the skin of a subject at a lancing site, and compressing a ribbed contact face of the lancing device against the skin adjacent the lancing site.
6. The method of Claim 6, further comprising twisting the ribbed contact face in contact with the skin.

ABSTRACT

A tip portion or end cap for a lancing device having an opening for passing a lancet tip formed therein, and a contact face with a plurality of spaced ribs adjacent the opening.

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Fig. 12 a

All Concave

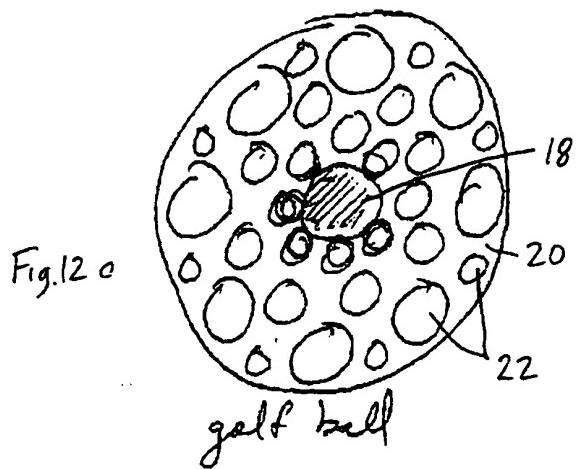
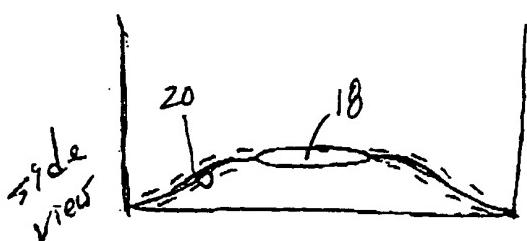


Fig. 12 c

Fig. 12 b

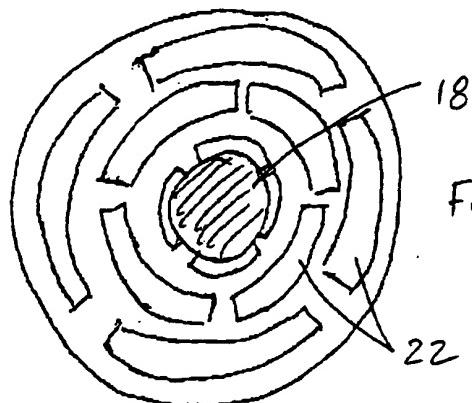
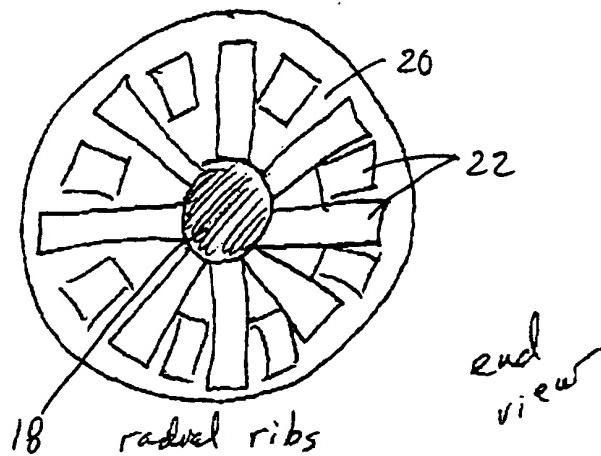
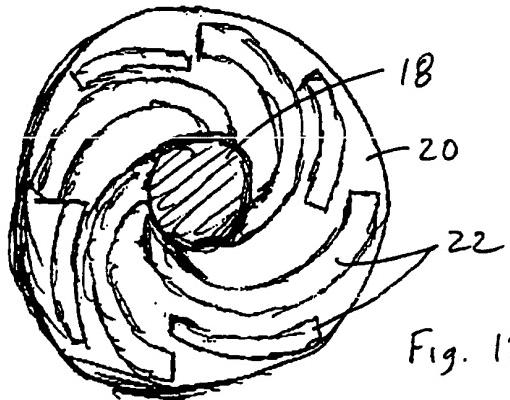


Fig. 12 d



spiral ribs

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Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/US04/024281

International filing date: 28 July 2004 (28.07.2004)

Document type: Certified copy of priority document

Document details: Country/Office: US
Number: 60/499,818
Filing date: 03 September 2003 (03.09.2003)

Date of receipt at the International Bureau: 27 August 2004 (27.08.2004)

Remark: Priority document submitted or transmitted to the International Bureau in
compliance with Rule 17.1(a) or (b)



World Intellectual Property Organization (WIPO) - Geneva, Switzerland
Organisation Mondiale de la Propriété Intellectuelle (OMPI) - Genève, Suisse